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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/855,036 05/01/92 REEVE

M 263-GB910021

18N1/0203

EXAMINER
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ART UNIT 8

PAPER NUMBER

1815

DATE MAILED: 02/03/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

This application has been examined Responsive to communication filed on 6/21/93 This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. Notice of References Cited by Examiner, PTO-892.
2. Notice of Draftsman's Patent Drawing Review, PTO-948.
3. Notice of Art Cited by Applicant, PTO-1449.
4. Notice of Informal Patent Application, PTO-152.
5. Information on How to Effect Drawing Changes, PTO-1474.
6.

Part II SUMMARY OF ACTION

1. Claims 3, 9-10, 13-20 are pending in the application.

Of the above, claims 17-20 are withdrawn from consideration.

2. Claims _____ have been cancelled.

3. Claims _____ are allowed.

4. Claims 3, 9-10, 13-20/18 are rejected.

5. Claims _____ are objected to.

6. Claims _____ are subject to restriction or election requirement.

7. This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. Formal drawings are required in response to this Office action.

9. The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are acceptable; not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been approved by the examiner; disapproved by the examiner (see explanation).

11. The proposed drawing correction, filed _____, has been approved; disapproved (see explanation).

12. Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has been received not been received been filed in parent application, serial no. _____; filed on _____.

13. Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. Other

EXAMINER'S ACTION

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1. Examiner acknowledges the amendment, response, declaration and Information Disclosure of 10/20/93.

Claims 3, 9-10 and 13-20 remain pending and are subject to restriction requirement.

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2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

10 I. Claims 3, 9-10 and 13-18, drawn to a method and apparatus for separating cellular components, classified in Class 435, subclass 270.

II. Claims 19-20, drawn to a magnetic bead, classified in Class 252, subclass 62.51.

The inventions are distinct, each from the other because of the following reasons:

15 Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the process can be practiced with another materially different product such as the polymer coated beads cited on page 5 of the specification.

Because these inventions are distinct for the reasons given

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above and because of their recognized divergent subject matter restriction for examination purposes as indicated is proper.

Newly submitted claims 19-20 are directed to an invention that is independent or distinct from the invention originally 5 claimed for the reasons cited above.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 19-20 are withdrawn from 10 consideration as being directed to a non-elected invention. See 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03.

This application contains claims 19-20 drawn to a non-elected invention. A complete response to the final rejection must include cancellation of non-elected claims or other 15 appropriate action (37 C.F.R. § 1.144) M.P.E.P. § 821.01.

Claims 3, 9-10 and 13-18 are considered on the merits.

3. Acknowledgment is made of applicant's properly executed declaration of 10/20/93.

20

4. Claims 3 and 9-10 are objected to as being dependent upon cancelled claims.

5. The text of those sections of Title 35, U.S. Code not

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included in this action can be found in a prior Office action.

any soln w/ NA

Claims 14 and 16 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is fully enabling only for claims limited to the procedures demonstrated in Examples 1-3. These examples show, apparently successfully, the present method applied to a variety of target substances: a sample of nucleic acid, a sample of nucleic acid with protein and a sample of phage. Each of these examples was performed on a clean, artificial mixture of the target substance and the qualitative results were stated.

*Issue chart
Var not used
Ex 10*

The remaining examples are speculative in nature as they appear to be laboratory protocols presented without even qualitative results. The present disclosure is not adequate to enable the many other biopolymers, let alone non-biopolymers, encompassed by the present claim language. For instance, the isolation of nucleic acid from lysate or the isolation of blood cells from whole blood present far more challenging and impure mixtures than those demonstrated to date. See M.P.E.P. §§ 706.03(n) and 706.03(z).

6. Claims 3, 9-10 and 13-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

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regards as the invention.

The following terms lack proper antecedent basis in the claims: "solution" in line 5 of claim 13; "impure solution" in line 5 of claim 14; "protein" and "suspended magnetically 5 attractive particles" in lines 5 and 6 of claim 15; "cell lysate" in line 13 of claim 16 for the "bacteriophage, virus"; and the "solution" of line 6 in claim 18.

Claim 16 is unclear in associating the protein, etc. with the beads after the beads have already been drawn down.

10 The purpose for the pre-treatment of claim 17 should be set forth.

✓ Claim 18 is confusing as it appear to be written as a method claim.

15 7. In light of the amendments to 10/20/93, claims 3 and 9 are no longer rejected under 35 U.S.C. § 102(b) as anticipated by Warren et al (USP 3470067).

20 8. In light of the amendments to 10/20/93, claim 3 is no longer rejected under 35 U.S.C. § 102(b) as anticipated by Mitchell et al (USP 4001197).

✓ 9. Claim 18 is rejected under 35 U.S.C. § 102(b) as anticipated by Mitchell et al (USP 4001197).

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See the abstract, column 2 and Figure 1 of Mitchell et al. Here is taught the use of magnetic particles to non-specifically bind to microorganism cells to separate them from a fluid medium. Examiner notes that the automatic valve and magnetic separator of 5 Figure 1 read on the automatic pipette and magnet of the present claim 18 because the disclosed structure is the same and because the apparatus of Mitchell et al is capable of being used in the method steps set forth in claim 18.

10 ✓10. Claims 13-14 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Lyle et al (Reference BF).

See pages 4-5, lines 30-40 of page 7 and Example 11 of Lyle et al. Lyle et al teach the removal of nucleic acid from cell 15 lysate by use of magnetic, non-specifically binds spheres. The reference appears to teach all the steps of the claims. What of the steps is not taught would have been obvious to one seeking to separate the nucleic acid from the lysate.

20 11. No claims are allowed.

Applicant's amendment necessitated the new grounds of rejection. Therefore, THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the

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shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

5 A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

10 15 The remaining references listed on the enclosed PTO-1449 are cited to further show the state of the art.

20 Any inquiry concerning this communication or earlier communications from the examiner should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

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Timothy J. Reardon
January 24, 1994


MICHAEL G. WITSHYN
SUPERVISORY PATENT EXAMINER
GROUP 1800